IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA

v.

Criminal Action No.
1:09-CR- 411 (TJM)

THE PLASTIC SURGERY GROUP, LLP,

Defendant.

****

ANDREW T. BAXTER, United States Attorney for the Northern District of New York (by Thomas A. Capezza and Jason S. Hadges, appearing) and THE PLASTIC SURGERY GROUP, LLP (with E. Stewart Jones, Esq., appearing) hereby enter into the following Plea Agreement regarding the disposition of a criminal charge against the Defendant:

1. **Defendant's Promises.** In return for the consideration described below, THE PLASTIC SURGERY GROUP, LLP ("TPSG") agrees as follows:

a. The Defendant will waive indictment and enter a plea of guilty to a one-count Information charging TPSG with misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2).

b. The Defendant consents to the entry of an order directing TPSG to pay restitution in full to any person who would qualify as a victim, under 18 U.S.C. § 3663 or § 3663A, of the following offense(s), whether or not the offense(s) are encompassed in the offense of conviction: misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2).

c. The Defendant consents to the entry of an order directing TPSG to forfeit certain assets to the United States, pursuant to the forfeiture allegation in the information.

2. **Potential Penalties.** THE PLASTIC SURGERY GROUP, LLP understands that the potential penalties for misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2) are:

a. Maximum Term of Imprisonment: 3 years. (21 U.S.C. § 333(a)(2))

b. Mandatory Minimum Term of Imprisonment: none.

c. Supervised Release: In addition to imposing any other penalty, the sentencing Court may require the Defendant to serve a term of supervised release of up to 1 year, to begin at the expiration of any term of imprisonment imposed upon a given defendant. 18 U.S.C. § 3583. Under some circumstances, the Court may also extend the term of supervised release, and it may modify, reduce, or enlarge the conditions of such release.

d. Maximum Fine: $500,000. (18 U.S.C. § 3571(c) (3)) In its discretion, the Court may impose an alternative fine of the greater of twice the pecuniary gain to the Defendant or loss to any victim resulting from the offense of conviction. (18 U.S.C. § 3571(d))

e. Mandatory Restitution: The sentencing Court may order that the Defendant pay restitution to any victim of the offense of conviction. (18 U.S.C. §§ 3663 & 3664)

f. Forfeiture: The sentence imposed by the Court may include an order of forfeiture.

g. Special Assessment: The Defendant will be required to pay an assessment of $100, which is due and payable at the time of sentencing. (18 U.S.C. § 3013) The Defendant

agrees to deliver a check or money order to the Clerk of the Court in the amount of $100, payable to the U.S. District Court at the time of his sentencing.

h. Interest and Penalties: Interest and penalties may accrue, as a matter of law, on any unpaid financial obligation imposed as part of the Defendant's sentence, from as early as the date of sentencing.

i. Collateral Consequences: Conviction of a felony may result in the loss of certain civil rights, including, but not limited to, the right to vote or the right to possess firearms.

3. **Sentencing Factors.** THE PLASTIC SURGERY GROUP, LLP understands that the sentence to be imposed upon TPSG is within the discretion of the sentencing Court, subject to the statutory maximum penalties and the provisions of the Sentencing Reform Act and the United States Sentencing Guidelines promulgated thereunder, as modified by *United States v. Booker*, 543 U.S. 220 (2005). While the Court is not ultimately bound to impose a sentence within the applicable Sentencing Guidelines range, it must take into account the Sentencing Guidelines, along with the other factors set forth in 18 U.S.C. § 3553(a). The United States Attorney's Office will ask the Court to apply the Guidelines in effect on the date of sentencing, pursuant to 18 U.S.C. § 3553(a)(4)(A)(ii) and U.S.S.G. § 1B1.11, even if the application of the Guidelines in effect at the time the defendant committed the offense would generate a lower sentencing range.

4. **Elements of the Offense.** THE PLASTIC SURGERY GROUP, LLP understands the following legal elements of the offense stated in misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2), and admits that those elements accurately describe TPSG's criminal conduct:

a. The article is a drug;

b. an act was done to the drug that resulted in the drug being misbranded;

c. while the drug was held for sale after shipment in interstate commerce; and

d. with the intent to defraud or mislead.

See 21 U.S.C. § 331(k); United States v. Sullivan, 332 U.S. 689, 695 (1948); United States v. Gel Spice Co., 601 F. Supp. 1205, 1210 (E.D.N.Y. 1984).

5. **Factual Basis for the Plea.** THE PLASTIC SURGERY GROUP, LLP admits the following facts, which establish TPSG's guilt with respect to the offense of misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2):

a. The FDA regulates the manufacture and distribution of drugs in the United States. The FDA also regulates the manufacture and distribution of "biological products," which includes toxins used for the "prevention, treatment, or cure of a disease or condition of human beings."

i. The FDA has established approval procedures for evaluating both new drugs and biological products. As regards biological products, this process is technically known as licensing.

ii. Approval is required for each new drug intended for human use before its sale is permitted. Likewise, a license is required for each new biological product before its sale is permitted.

b. Botulinum Toxin Type A meets the definitions of both "drug" and "biological product," and is thus regulated as both a drug and a biological product.

i. Accordingly, no form of Botulinum Toxin Type A can be legally distributed in interstate commerce for use on humans unless it is either licensed by the FDA as a biological product or approved as a new drug.

ii. No new drug or biological product can be distributed in interstate commerce for use on humans unless it has obtained FDA approval.

c. There is only one Botulinum Toxin Type A product that was approved by FDA prior to 2009; this product was first approved in 1989. In 1991, Allergan, Inc. ("Allergan"), purchased the rights to this product and began to market it under the name BOTOX®.

i. Subsequently, Allergan received additional approvals to market BOTOX® for other indications. In April 2002, Allergan obtained a license from the FDA for a new drug and biological product called "BOTOX® Cosmetic" for use on humans to treat facial wrinkles.

ii. "BOTOX® Cosmetic" uses Botulinum Toxin Type A to temporarily smooth facial lines by paralyzing or weakening the muscles that contract to cause facial wrinkles. BOTOX® Cosmetic is administered through a hypodermic needle, which allows a physician to place the medication in precisely the right place to affect the nerves which stimulate muscle contractions. Once in the body, Botulinum Toxin Type A binds to nerve endings at the point where the nerves join muscles. This prevents the nerves from signaling the muscles to contract.

d. Toxin Research International, Inc. ("TRI") is a company based in Arizona. TRI distributed a form of Botulinum Toxin Type A (hereafter "TRI-toxin"), which was approximately one-half the price of BOTOX® and BOTOX® Cosmetic.

i. The TRI-toxin had not been approved or licensed for use on humans by the FDA (nor has it ever been).

ii. The label placed on vials of TRI-toxin included the warning: "For Research Purposes Only, Not for Human Use." Invoices accompanying all TRI-toxin shipments included the same warning.

e. Defendant TPSG is a limited liability partnership whose members consisted of professional corporations organized under the laws of New York State. The medical offices of TPSG are located in Albany, in the State and Northern District of New York.

f. From approximately 2001 through early February 2004, TPSG offered, at its medical offices, Botulinum Toxin Type A injections for the treatment of facial wrinkles using genuine BOTOX® and BOTOX® Cosmetic.

g. In or about January 2004, WILLIAM F. DE LUCA, Jr., a physician whose professional corporation was a partner of TPSG, received a flyer in the mail from TRI advertising the TRI-toxin. WILLIAM F. DE LUCA, Jr., gave the flyer to TPSG's supervisory nurse, and told her to order TRI-toxin. During the period January 2004 through November 2004, the supervisory nurse, pursuant to the authorization of Dr. WILLIAM F. DE LUCA, ordered and obtained at least 31 vials of TRI-toxin from TRI.

i. Each vial was labeled as containing 500 International Units ("IUs") of toxin, for a total of 15,500 units of toxin, a different amount than the vials of BOTOX® and BOTOX® Cosmetic products that had been previously used.

ii. The supervisory nurse instructed the nurses as to the amount of dilution for the TRI-toxin, which necessarily required the nurses to handle the vials with the warning label referenced above.

iii. TPSG's practice administrator caused payment for several of the TRI-toxin purchases to be made on his credit card.

h. Starting in approximately February 2004, defendant TPSG ceased using the FDA-approved BOTOX® and BOTOX® Cosmetic and began exclusively using TRI-toxin on its patients seeking treatments with Botulinum Toxin Type A for facial wrinkles.

i. From in or about February 2004 though December 2004, five (5) physicians, whose professional corporations were partners of TPSG (the "treating physicians"), with the assistance of TPSG nurses, injected approximately one hundred and fifty (150) patients with TRI-toxin, not BOTOX® or BOTOX® Cosmetic.

j. The conduct, knowledge, and intent of the treating physicians, nurses, and practice administrator, considered collectively, are sufficient to establish that Defendant TPSG knew that TSPG was administering a substance other than FDA-approved Allergan BOTOX® or BOTOX® Cosmetic to its patients from in or about February 2004 through December 2004.

k. Defendant TPSG never disclosed to any patient that they were being injected with a product other than BOTOX® or BOTOX® Cosmetic. TPSG received a May 27, 2003 letter from Allergan expressly stating "The BOTOX® and BOTOX® Cosmetic registration is exclusive to Allergan, Inc." and "The BOTOX® brand name **should not be used as a generic term** nor is it used in an abbreviated form or as a synonym for a product in the same class" (emphasis in original). Nonetheless, defendant TPSG repeatedly misled patients into believing they were being treated with an FDA-approved BOTOX® and BOTOX® Cosmetic substance, when in fact they were being injected with TRI-toxin.

i. Defendant TPSG displayed, in its offices, brochures and other promotional materials created by Allergan to promote FDA-approved BOTOX® and BOTOX® Cosmetic during the period that it administered TRI-toxin, not Allergan-manufactured BOTOX® and BOTOX® Cosmetic, on patients.

ii. Defendant TPSG gave a "consent form" to over 100 patients that stated that defendant TPSG would use "BOTOX" when defendant TPSG did not in fact administer BOTOX® and BOTOX® Cosmetic to those patients. The consent form further explained that BOTOX is approved by the FDA, although TPSG was then using an unapproved substitute.

iii. During the period February 2004 through December 2004, defendant TPSG created billing records that made reference to"BOTOX" treatments, when, in fact, defendant TPSG used a substitute, unapproved botulinum toxin on those patients.

iv. Defendant TPSG stated on its website, *www.theplasticsurgerygroup.net*, that TPSG offered "Botox Seminars" and "Botox" during the period that TPSG used a non-FDA approved substitute botulinum toxin on patients seeking BOTOX® and BOTOX® Cosmetic treatments.

v. During the period February 2004 through June 2004, defendant TPSG conducted monthly "Botox" Seminars for members of the public; when in fact the defendant TPSG used a substitute unapproved botulinum toxin on patients seeking BOTOX® and BOTOX® Cosmetic treatments.

l. Despite all the indications that patients seeking such treatments would be injected with BOTOX® nor BOTOX® Cosmetic, defendant TPSG in fact injected patients with TRI-toxin, a cheaper form of Botulinum Toxin Type A that had not been approved by the FDA for

use on humans. Notwithstanding the lower cost of the TRI-toxin to TPSG, patients were charged for the TRI-toxin the same dollar amount they were charged for BOTOX® and BOTOX® Cosmetic. These patients paid a total of over $100,000 for these treatments during the period in 2004 when TPSG was administering TRI-toxin.

m. On December 13, 2004, following news reports raising concerns about TRI-toxin, defendant TPSG stopped using the TRI-toxin and resumed purchasing and injecting patients with the Allergan-manufactured BOTOX® and BOTOX® Cosmetic on patients. Defendant TPSG did not notify any of the more than one hundred and fifty (150) patients that they had been injected with the unapproved TRI-toxin.

n. Defendant TPSG did not respond, prior to interviews conducted at the offices of TPSG by Special Agents of the FDA in February 2005, to an "Urgent: Botulinum Toxin Type A Recall" notice initiated by court order from the United States District Court, Southern District of Florida.

o. On or about April 26, 2004, in the Northern District of New York, defendant TPSG, with the intent to mislead (established by the collective conduct, knowledge, and intent of its agents), misbranded a drug, namely, Botulinum Toxin Type A manufactured by Toxin Research International, Inc. in Arizona (hereinafter, "TRI-toxin"), while it was held for sale and after shipment in interstate commerce, in that defendant TPSG in connection with the injection of a patient offered the TRI-toxin for sale to a patient under the name of another drug, namely BOTOX®/ BOTOX® Cosmetic.

The Defendant understands that the sentencing Court may make factual findings with respect to any and all sentencing factors and issues, including those referenced in the United States

Sentencing Guidelines, whether or not such factors or issues have been admitted by the Defendant or stipulated by the parties. In making those findings by a preponderance of the evidence, the Court may consider any reliable evidence, including hearsay. The Defendant agrees that TPSG's sentence may be determined based upon such judicial fact-finding.

6. **Use of Defendant's Admissions.** The Defendant agrees that the statements made by TPSG in signing this Agreement, including the factual admissions set forth above in paragraph 5, shall be admissible and useable against the Defendant by the United States in any subsequent criminal or civil proceeding, even if TPSG fails to enter a guilty plea pursuant to this Agreement, or if such a guilty plea is later vacated or withdrawn. The Defendant waives any rights under Fed. R. Crim. P. 11(f) and Fed. R. Evid. 410, to the extent these rules are inconsistent with this paragraph or with this Agreement generally.

7. **Collection of Financial Obligations.** In order to facilitate the collection of financial obligations to be imposed in connection with this prosecution, the Defendant agrees fully to disclose all assets in which he has any interest or over which the Defendant exercises control, directly or indirectly, including those held by a spouse, nominee or other third party.

a. The Defendant will promptly submit a completed financial statement to the U.S. Attorney's Office, in a form it provides and as it directs. The Defendant promises that his financial statement and disclosures will be complete, accurate and truthful.

b. The Defendant expressly authorizes the U.S. Attorney's Office to obtain a credit report on TPSG in order to evaluate the Defendant's ability to satisfy any financial obligation imposed by the Court.

8. **Government's Promises and Reservation of Rights.** In exchange for the plea of guilty to misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2) by THE PLASTIC SURGERY GROUP, LLP and TPSG's continuing compliance with all of the terms of this Plea Agreement, the United States Attorney's Office for the Northern District of New York agrees as follows:

a. It will bring no further federal criminal charges against the Defendant relating to the conduct in the Northern District of New York, committed before the date of this Agreement, which is described as misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2) and the Defendant's admissions in paragraph 5, above, for so long as the guilty plea and sentence on misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2) remain in effect.

b. If the guilty plea to misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2) is later withdrawn or vacated, the charges dismissed or not prosecuted pursuant to subparagraph(s) 9a and 9b of this Agreement may be filed and prosecuted, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the filing of any such charges. The Defendant waives any defense or objection to the filing and prosecution of any such charges that are not time-barred by the applicable statute of limitations as of the date of this Agreement.

c. It reserves the right to recommend a specific sentence within the applicable Guidelines range determined by the Court.

d. The U.S. Attorney's Office reserves the right to advise the sentencing Court and the Probation Office of any information, in aggravation or mitigation of sentencing, whether or

not encompassed within misbranding a drug, in violation of 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2), subject only to the limitations imposed by U.S.S.G. § 1B1.8.

9. **Stipulations.** The U.S. Attorney's Office and THE PLASTIC SURGERY GROUP, LLP agree to stipulate at sentencing to the statement(s) set forth in subparagraph a below, subject to the caveats set forth in the subparagraphs following:

a. Stipulations

i. The U.S. Attorney's Office will recommend a 2-level downward adjustment to the applicable Sentencing Guidelines range if, (A) through the time of sentencing, the Defendant clearly demonstrates "acceptance of responsibility" to the satisfaction of the Government for the offense [of conviction], as defined in U.S.S.G. § 3E1.1(a); and (B) the Government does not learn of new evidence of conduct committed by the Defendant, either before or after TPSG's guilty plea, that constitutes "obstruction of justice," as defined in U.S.S.G. § 3C1.1. If the Defendant clearly demonstrates "acceptance of responsibility" to the satisfaction of the Government and promptly enters a plea of guilty, thereby permitting the U.S. Attorney's Office to avoid preparing for trial and permitting the Government and the Court to allocate their resources efficiently, the U.S. Attorney's Office will move for an additional downward adjustment of 1 level, if the Defendant otherwise qualifies under U.S.S.G. § 3E1.1(b).

ii. Defendant TPSG agrees to pay a fine of $200,000.

b. Until the Probation Office has fully investigated the defendant's criminal history, it is not possible to predict with certainty the Defendant's Criminal History Category and, in some cases, TPSG's total offense level.

c. It is understood that these stipulations cannot and do not bind the sentencing Court, which may make independent factual findings by a preponderance of the evidence and may reject any or all stipulations between the parties. The rejection of any or all stipulations by the Court will not be the basis for the withdrawal of a plea of guilty by the Defendant, and will not release either the U.S. Attorney's Office or the Defendant from any other portion of this Agreement, including any other stipulations agreed to herein.

d. No stipulation in this Agreement shall affect the parties' respective obligations to ensure that, to the extent possible, the Court has all information pertinent to its determination of an appropriate sentence. The parties may provide any such factual information to the Probation Office and/or to the Court, without limitation, before or after the completion of the Presentence Investigation Report, and agree that the submission of such information shall not be deemed "advocacy" in violation of any stipulation in this Agreement.

e. To the extent the stipulations above do not reflect agreement on any factor or issue potentially affecting the applicable advisory Sentencing Guidelines range, the Defendant and the U.S. Attorney's Office each expressly reserves the right to advocate if, and how, any such factor or issue would apply under the Sentencing Guidelines.

10. **Preliminary Sentencing Guidelines Estimates.** The Defendant understands that any estimate of the Defendant's total offense level, criminal history score, and/or Sentencing Guidelines range provided before sentencing is preliminary and is not binding on the parties to this Agreement, the Probation Office, or the Court.

11. **Remedies for Breach.** Should the U.S. Attorney's Office determine that the Defendant, after the date of this Plea Agreement, (i) has committed any further crime or violated any

condition of release or supervision imposed by the Court (whether or not charged); (ii) has given false, incomplete, or misleading testimony or information; or (iii) has otherwise breached any condition of this Agreement, the U.S. Attorney's Office will have the right, in its sole discretion, to void this Agreement, in whole or in part. In the event of any such breach, the Defendant will not be permitted to withdraw the guilty plea under this Agreement, but will thereafter be subject to prosecution for any federal criminal violation of which the U.S. Attorney's Office has knowledge, including but not limited to charges that this Office has agreed to dismiss or has agreed not to prosecute.

a. The Defendant waives any defense or objection to the commencement of any such prosecution that is not time-barred by the applicable statute of limitations as of the date of this Agreement, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the commencement of any such prosecution.

b. Moreover, in connection with any such prosecution, any information, statement, or testimony provided by the Defendant, and all leads derived therefrom, may be used against TPSG, without limitation.

c. In the event of any such breach by the Defendant, the U.S. Attorney's Office will have the right, in its sole discretion, to do the following, notwithstanding any contrary provision or stipulation in this Plea Agreement:

i. to advocate if, and how, any particular adjustment or specific offense characteristic affects the applicable Sentencing Guidelines range;

ii. to utilize any information, statement, or testimony provided by the Defendant in determining the applicable Sentencing Guidelines range, notwithstanding U.S.S.G. § 1B1.8;

iii. to recommend a specific sentence of imprisonment within or above the applicable Sentencing Guidelines range determined by the Court.

12. **Limitations on Agreement.** This Agreement is limited to the U.S. Attorney's Office for the Northern District of New York and cannot bind other federal, state or local prosecuting or administrative authorities. Furthermore, this Agreement does not prohibit the United States, any agency thereof, or any third party from initiating or prosecuting any civil or administrative proceedings directly or indirectly involving the Defendant, including, but not limited to, proceedings by the Internal Revenue Service relating to potential civil tax liability or proceedings relating to the forfeiture of assets.

13. **Agreement Not Binding on the Court.** The Court is neither a party to, nor bound by this Agreement. The Court may accept or reject this Plea Agreement or defer a decision until it has considered the Presentence Investigation Report prepared by the U.S. Probation Office.

a. If the Court rejects the provisions of this Agreement permitting the Defendant to plead guilty to 21 U.S.C. §§ 331(k), 352(i)(3), and 333(a)(2) in satisfaction of other charges, which provisions were negotiated pursuant to Fed. R. Crim. P. 11(c)(1)(A), the Court will afford the Defendant an opportunity to withdraw the plea of guilty prior to sentencing, pursuant to Fed. R. Crim. P. 11(c)(5) & (d).

b. The Court is not bound by any recommendation, stipulation, or request made by the parties, pursuant to Fed. R. Crim. P. 11(c)(1)(B), as to the appropriate sentence, and the

Defendant may not withdraw the plea of guilty if the Court declines to follow any such recommendation, stipulation, or request. The U.S. Attorney's Office reserves the right to support and defend, in connection with any post-sentencing proceedings, any decision the Court may make with regard to the Defendant's sentence, whether or not such decision is consistent with this Office's recommendations, stipulations, or requests.

14. **Waiver of Defendant's Rights.** The Defendant acknowledges that a representative(s) of TPSG has read each of the provisions of the entire Plea Agreement with the assistance of counsel and understands its provisions. The Defendant further acknowledges that the plea is voluntary and did not result from any force, threat, or promises other than the promises in this Plea Agreement.

a. The Defendant understands the right to assistance of counsel at every stage of the proceeding and has discussed his constitutional and other rights with defense counsel. The Defendant understands that by entering a plea of guilty, TPSG will be giving up the right (i) to be presumed innocent until proven guilty beyond a reasonable doubt; (ii) to plead not guilty; (iii) to trial by jury; (iv) to confront, cross-examine, and compel the attendance of witnesses at trial; (v) to present evidence in TPSG's defense; and (vi) to remain silent and refuse to be a witness against TPSG by asserting the privilege against self-incrimination.

b. The Defendant has been advised by defense counsel of the nature of the charges to which he is entering a guilty plea and the nature and range of the possible sentence. The Defendant understands the sentencing Court's obligation to consider the United States Sentencing Guidelines (as explained further above) and the Court's discretion to depart from those Guidelines

under some circumstances or otherwise to impose a reasonable sentence outside of the applicable Sentencing Guidelines range.

15. **Waiver of Appeal and Collateral Attack.** The Defendant acknowledges that, after consultation with defense counsel, TPSG fully understands the extent of TPSG's rights to appeal, and/or to collaterally attack the conviction and sentence in this case. The Defendant waives any and all rights, including those conferred by 18 U.S.C. § 3742 and/or 28 U.S.C. § 2255, to appeal or collaterally attack TPSG's conviction and any sentence, including any related issues with respect to the establishment of the advisory Sentencing Guidelines range or the reasonableness of the sentence imposed.

16. **Memorialization of Agreement.** No promises, agreements or conditions other than those set forth in this Agreement will be effective unless memorialized in writing and signed by all parties or confirmed on the record before the Court. This Agreement, to become effective, must be

signed by all of the parties listed below.

ANDREW T. BAXTER
United States Attorney
Northern District of New York

Dated: 8/11, 2009 By: Thomas A. Capezza
Thomas A. Capezza
Assistant U.S. Attorney
Bar Roll No.

Jason S. Hadges
Special Assistant U.S. Attorney

Dated: 7/28, 2009

THE PLASTIC SURGERY GROUP, LLP
Defendant by the group's Secretary
and Treasurer, Douglas M. Hargrave, M.D.

Dated: 7/28, 2009

E. Stewart Jones, Esq.
Attorney for Defendant
Bar Roll No.